REMARKS

This Amendment After Final Rejection is being submitted in response to the Office Action mailed on August 4, 2009. When this amendment is entered, claims 1 and 20 will be amended. Claims1-3, 5, 7, 8, 10, 11, 14, 19 and 20 remain pending in this application. Entry of this amendment and reconsideration of this application are respectfully requested.

Claims 1-3, 5, 7, 8, 10,11, 14, 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,494,852 (Barak, et al.) in view of U.S. Patent No. 4,624,244 (Taheri). Applicants respectfully traverse this rejection.

Barak, et al. is concerned with making a portable device. As previously discussed, Barak, et al. is directed to a device in which the thickness of the sleeve is reduced by providing interconnected compartments within each cell. The approach Barak, et al. has taken to making the device portable is to focus on reducing the thickness of the sleeve so that a reduced volume of air is needed to apply a suitable pressure to the limb. Barak, et al. has not been concerned with reducing the number of cells by identifying which cells are instrumental to the operation of the device. Moreover, the device of Barak, et al. includes one or more cells applied to the thigh. Applicants' claimed invention focuses on providing cells below the knee of the patient in order to provide effective treatment to the patient. Barak, et al. suggests that the number of cells can vary, but says nothing concerning the positions of those cells. Barak, et al. presents the device as including a thigh cuff. (See, for example, Figs. 1 and 2.) Given that Barak, et al. is concerned with making the device portable, and this is done by reducing the thickness of the sleeve so that a reduced volume of air is needed to apply pressure, it follows that if Barak, et al. believed the device would be effective without the presence of a thigh cuff, it would have been eliminated. It is not. Thus, from reading Barak, et al., one of ordinary skill in the art would believe that it is essential to pressurize the thigh in order to obtain benefit from that device. If Barak, et al. would have believed otherwise, the device would have ended below the knee.

It is asserted in the Action that Barak, et al. teaches that it would have been obvious to limit the Barak, et al. device to include only a below the knee leg cuff and a

foot cuff like the device in Taheri. However, Barak, et al. does not teach that treatment only below the knee is effective. The Barak, et al. device, for use on the leg, has a thigh cuff and a lower leg cuff. It is nowhere suggested that the thigh cuff can be eliminated. Moreover, the cells in Barak, et al. are independently controllable. Consequently, if the user wanted to treat only below the knee, it would be possible to use the full sleeve with thigh and lower leg cuff to do so merely by programming the controller to inflate only the lower leg cells. The thigh cuff would still be present. Barak, et al., however, does not suggest this. In fact, the opposite is taught. From the passage at column 6, line 63, through column 7, line 4, it is apparent that for a sleeve with a thigh and lower leg cuff with six cells, the control unit operates as shown in Fig. 7. This involves all the cells. There is no suggestion in Barak, et al. that some of the cells need not operate.

The Action relies on the passage at column 4, lines 14 to 15, which states that the invention can be used on "a part of a leg". Applicants submit that the device shown in Figs. 1 and 2 of Barak, et al., ***is*** being used on a part of a leg in that the cuffs do not cover the knee, the ankle, or the upper thigh. The statement is therefore consistent with the device shown by Barak, et al., in Figs. 1 and 2 which includes a thigh cuff. The Examiner's attention is further drawn to the description of the prior art in Barak, et al. At column 1, lines 34 to 35, the prior art devices are described as "big and ungainly", and they are said to "restrict[s] the movement of the limb it encompasses". This passage suggests that the prior art devices are used on the whole leg and, taken in this context, the device of Barak, et al., as shown in Figs. 1 and 2, is used on part of a leg. One of ordinary skill in the art, reading the passage at column 4, lines 14 to 15, therefore would not be motivated to eliminate the thigh cuff of Barak, et al.

The Action also relies on the passage in Barak, et al., at column 10, lines 34 to 35, which states that "[T]he number of **cells** in the sleeve can vary, according to desired treatments" (emphasis added). In the context of Barak, et al., the word "cell" is used to describe the compartments or bladders in each cuff. See, for instance, Fig. 2 where the cells are labeled **2**. Further, see column 4, lines 25 to 29, where it is explained, "The sleeve **1** has an inner and outer surface composed of a durable flexible material and is divided into a plurality of cells **2** along its length and each cell is connected to the control unit **3**..." The passage at column 10, lines 34 to 35, is therefore saying that each **cuff**

can have any number of *cells*. It does not say that the number of **cuffs** can vary. It certainly does not say that the thigh cuff can be eliminated. Contrast this passage to Applicants' claims which specify that the device consists of a leg cuff and a foot cuff, the leg cuff consists of only three cells, and those three cells have stated positions. Barak, et al. is saying that any number is appropriate and gives no guidance on what is most effective.

Moreover, Applicants' claims require that the leg cuff consists of only three cells with stated positions, and that those three cells each consist of a single compartment. A significant difference between the cells of the claimed invention and those of Barak, et al., is that the cells of Barak, et al., are divided into longitudinal compartments which give the fluted profile on inflation as shown in Figure 4B of Barak, et al. Cells in the instant application are claimed as single compartments and are shown as single compartments in Figure 3, and it is clear from the language in claim 1 that each cell wraps around the limb and so is at least as large as the circumference of the limb.

Barak, et al., on the other hand, shows in Figs. 1, 2, 3, 4A and 4B that, although each cell wraps around the limb, it is divided into intra cell compartments. Claim 1 of Barak, et al., for example, expresses this as the cells including at least three intra-cell compartments (claim 1), each compartment being elongated along a long axis and being substantially rectangular in shape. At column 4, lines 47 onwards, the cells are said to be subdivided into a plurality of longitudinal compartments 7, and those compartments in a given cell are confluent due to perforations in the seams between the compartments so that all the compartments in a cell are inflated or deflated simultaneously. This is most readily seen in Figs. 4A and 4B. By contrast, the cells in the claimed invention consist of a single compartment so that the cell, when inflated, presents a smooth surface to the limb of the patient. The cells of Barak, et al., when inflated, present a fluted surface or a series of longitudinal peaks and troughs to the limb of the patient. An advantage of the smooth surface of the claimed invention is that the smooth surface applies an even compression to the limb and is more likely to apply that compression to the veins in the patient's limb. With the divided cells of Barak, et al., it is a matter of chance whether the compression applied to the limb by a peak in the inflation surface coincides with a vein underlying the patient's skin. The chances of

applying effective compression with the device of Barak, et al., are therefore much more hit and miss than with the single compartment cells of the claimed invention.

Next, there is a very large gap between the passages cited in the Action and the conclusion that one of ordinary skill would find it obvious to combine Barak, et al., and Taheri to treat the lower limb. Barak, et al., gives no indication that such a device would be effective. Moreover, the teaching of Barak, et al., overall is that the sleeve has both a thigh and a lower leg cuff. Barak, et al., does not suggest that it is possible to eliminate the thigh cuff and it certainly does not teach that doing so would make an effective device.

The Action further relies on the very general statement in Barak, et al. that - "Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention." This very general statement would not suggest to one of ordinary skill that the thigh cuff of the leg device could be omitted. Rather, one of ordinary skill would realize that many patents include this general statement and give the statement no weight.

Further, as already mentioned, Barak, et al., is concerned with making a portable device by reducing the thickness of the sleeve so that a reduced volume of air is needed to apply pressure. This allows a much smaller compressor to be used which permits the patient to be mobile.

Barak, et al., teaches in the background to his invention that prior art devices share at least the following disadvantages: They use the conventional main power supply (wall outlet), and thus impose total confinement on the patient during treatment. The pump unit is heavy (5-15 pounds), which makes it hard to maneuver and place in the vicinity of the patients. The pump unit is big and thus creates a storage problem, specifically in hospitals, in which a few units are stationed, usually in a special storage room. The sleeve is big and ungainly, and thus restricts the movement of the limb it encompasses and imposes an aesthetic discomfort. In addition, the use of multiple cells demands the use of multiple conduits (usually one for each cell) making the whole system more cumbersome and harder to maneuver. All of the aforementioned

disadvantages result in poor patient and therapist compliance, resulting in that the devices are used for treatment only of the most severe cases.

Barak, et al., also teaches that prior art devices need to be as big they are and use the conventional electrical outlets for the power supply since they all use the same basic shape of inflatable bladders for their sleeves. These devices use substantial amounts of fluid in order to inflate the sleeve and create the desired pressure in a timely manner.

Barak, et al., achieves its aim of a portable device by using a specific design of cell. The cells are divided into a number of longitudinal compartments and thus limit the volume of air needed by the device.

The Taheri device has many of the disadvantages already mentioned that Barak, et al. attempts to overcome. Thus, the person of ordinary skill would not, therefore, be motivated to adapt Barak, et al., to omit the thigh cuff and have the form and bladder type of Taheri since Barak, et al., has taught that such devices do not enable the patient to be mobile. The person of ordinary skill would not move away from the bladder design of Barak, et al., with its many compartments towards those of Taheri with one component since Barak, et al., teaches that a large compressor is needed with such a design.

Applicants' claims recite a wearable controller that generates and controls the flow of fluid in the device. Taheri does not disclose a wearable controller. Applicants' claims also recite that the leg cuff comprises three cells that wrap around the lower limb. Taheri does not disclose cells that wrap around the limb. From Taheri, it is clear that the cells (bladders) are restricted to covering the calf region of the leg in use (column 1, lines 50 and 51; column 2, lines 63 to column 3, line 3). The bladders in Taheri do not therefore wrap around the leg as required by instant claim 1.

Taheri describes a device with a sleeve, a compressor and electronic components noted as 70, 71 and 72 in the drawings. There is no disclosure that the compressor and other components are wearable. Applicants' claims require that the controller is portable and wearable. Wearable is an important limitation because it is that which allows Applicants' device to be used when the wearer is mobile as well as when the wearer is immobile. There is no indication in Taheri that the collection of units

66, 70, 71 and 72 are intended to be worn by the patient, nor that they even can be worn in use.

For all these reasons at least, it would not be obvious for the person of ordinary skill in the art to limit the Barak, et al., device as suggested.

Still, it is argued at page 6 of the Action that a physician treats areas in need of treatment and that, based on the teachings of the combined references, a skilled artisan would clearly recognize that Barak, et al., could be modified to treat a lower leg and foot without the need of the thigh region.

This argument overlooks that Barak, et al., describes its device as being suitable for use in reduction of edemas, vascular disorders and the prevention of DVT (column 2, line 45). These disorders generally have an underlying chronic cause, such as heart failure or diabetes, which affects the whole body. The physician typically will not, in such circumstances, treat an isolated spot on the body. For instance, to prevent DVT, the whole of the Barak, et al., device would be used, leg cuff *and* thigh cuff. There is no indication in Barak, et al., that the device could be used in the way suggested in the Action.

At least for these reasons, Applicants request that this rejection be withdrawn.

In view of the foregoing, entry of this amendment, reconsideration of the application, and allowance of the application with claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20, are all respectfully requested.

Respectfully submitted,

ConvaTec Inc.
Patent Department
100 Headquarters Park Drive
Skillman, NJ 08558

John M. Kilcoyne
Attorney for Applicants
Reg. No. 33,100
(908) 904-2372

Date: October 5, 2009